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Strategic Management of Innovative Development of the Russian Pharmaceutical Complex

Klunko Natalia¹

Conditions of strategic management by a pharmaceutical complex according to strategic priorities of its development and the current tendencies of development of the pharmaceutical market and the pharmaceutical industry are determined. The problems defining a choice of strategic alternatives in development of a pharmaceutical complex are considered. The complex of tool support of strategic management in the specified sphere is developed.

Keywords: pharmaceutical complex, strategic management, innovative development, pharmacy 2020.

Introduction

In the field of pharmaceutical strategic management are problems of development as a rule considered in a context of ensuring its competitive advantages.

Works of researchers of the theory of strategic management (A. Chandler, D. Alfred [2], I. Ansoff [4]) were published in the first half of the 1960th, and today world scientific literature on strategic management totals thousands publications.

Leading foreign scientists in the field of the theory of strategic management are: I. Ansoff [4], J.B. Barney [6], R.M. Grant [10], J.B. Quinn [7], M.E. Porter [11], A.D. Chandler [2] etc.

The defining role in formation of modern scientific tradition in the field of strategic management was played by productive dialogue with those economic theories which considered a role of managers (the internal organization) in distinctions of results of firms

¹ PHD in business administration, doctoral candidate of St.-Petersburg University Management and Economy / Russia, E-mail: chief-nata@yandex.ru

and/or actively applied the model device to studying of the contract relations and competitive interactions. Among foreign authors of these theories helping development of researches of the major problems of strategic management – diversification, vertical integration, the corporate governance, competitive strategy, organizational training, etc., it is necessary to mark out M. Aoki, A.M. Brandenburger [1], I. Novaka [5], B. Kogut, U. Zander [3].

Among the Russian economists developing these theories and their appendices or original perspective theories of the company, S.B. Avdasheva, G.B. Kleyner, Yu.B. Kochevrin, Ya.I. Kuzminov, O.V. Lazareva, A.K. Lyasko, A.N. Oleynik, N.V. Rozanova, Ya.V. Sergiyenko, Yu.V. Fedotov.

Problems of the Russian pharmacy

Strategic approach to public administration by development of a pharmaceutical complex doesn't raise doubts of that for the present stage of its development a number of the problems determined both by the general economic globalization, and internal problems of the Russian pharmacy is characteristic.

1. The pharmaceutical branch makes a key contribution to the progress of medicine connected with transformation of basic researches in the sphere of innovative medicines.
2. The pharmaceutical branch has the undoubted institutional importance, acting as one of the most important sectors of the world economy, seriously influencing a situation in adjacent branches of economic activity – health care, insurance business, financial sector. Science intensity of pharmaceutical production promotes development of intersectoral communications of the enterprises of pharmaceutical industry with other branches of production of goods, such, as biotechnology, power, defense industry complex [8].
3. The pharmaceutical branch is characterized by high extent of monopolization when some tens leading multinational pharmaceutical companies (so-called “Big Pharma”) supervise considerable part of the most highly profitable segments of the branch market.
4. Width of the commodity range and science intensity pharmaceutical productions (any country of the world isn't able to develop and make now completely independently all range of necessary medicines) along with a high ratio of parameters of the price of medicines to the

cost of their transportation do pharmaceutical branch of one of the most globalized branches of world economy.

5. For the Russian pharmaceutical complex lack of accurately certain and realized purposes of strategic development of branch is characteristic.

Strategic management of a pharmaceutical complex

Priorities of strategic management of a pharmaceutical complex are determined by in “Strategy for the development of the pharmaceutical industry of the Russian Federation between now and 2020” (Pharma 2020) [13] which gives the chance for a choice of real strategic priorities, for the analysis of mechanisms and opportunities of adaptation of a pharmaceutical complex to environmental conditions.

In the Strategy “Pharma 2020” three basic scenarios of development of a pharmaceutical complex are defined: 1 . Inertial scenario. 2 . Investment scenario. 3 . Innovative scenario.

As it is specified in Strategy, the inertial scenario corresponds to passive strategy of the state in relation to pharmaceutical branch where the state doesn't provide additional investments.

The investment scenario correspond to moderate participation of the state in development and stimulations of pharmaceutical branch, is based on implementation of regulatory actions for the organization of production of generic preparations in the territory of the Russian Federation and purchase of licenses for the medicines, not having domestic analogs at the foreign companies.

The innovative scenario assumes significant growth in investments and acceleration of investment process. On the basis of the analysis of Strategy it is possible to draw a conclusion that in principle, prospects of development of the Russian pharmaceutical complex are connected with the volume of investment, as defines an alternative set of scenarios considered in Strategy.

The Strategy is seen as an instrument that provides for a transition of the domestic pharmaceutical industry to innovative model of development and the solution of the following tasks:

- technological re-equipment of the domestic pharmaceutical industry and creation of scientific-research base of world level;
- production of the domestic pharmaceutical industry socially significant medicinal products with the purpose of import substitution;
- the emergence to the market of innovation products manufactured by the domestic pharmaceutical industry
- increase of the export potential of the domestic pharmaceutical industry.
- staffing of the domestic pharmaceutical industry transition to innovative model of development.

Financing of the pharmaceutical industry with Program aim in the existing conditions it is optimal for the state modernization policy.

This tool during the project period of time will allow the state to concentrate on problem areas of organizational and financial resources, and after reaching the set goals easily reduce the state support with the transition to a market regulation of industries.

The main result of the implementation of the Strategy should be to increase the share of domestic pharmaceutical production by 2020. In the total volume of consumption in the domestic market, the share of domestic products will increase:

- up to 50% in terms of money;
- up to 90% of strategically important medicines and vital and essential medicinal products;
- up to 90% of strategically important medicines and vital and essential medicinal products.

The value of the Russian pharmaceutical complex is predicted to rise from \$25 billion by 2011 to \$75 billion by 2020, according to Cegedim Relationship Management's aggregated opinion from industry experts, government employees and analysts [12].

To achieve the stated objectives the main tasks are:

- increase of competitiveness of the domestic pharmaceutical industry through the harmonization of Russian standards in development and manufacturing of medicines with the international requirements;

- stimulation of development and manufacture of innovative medicines and support of export of Russian medicines, including through the elaboration of additional funding mechanisms original developments;
- the protection of the domestic market from unfair competition and alignment of conditions of access to the market for domestic and foreign manufacturers;
- implementation of technological re-equipment of the Russian pharmaceutical industry;
- improvement of the system of conformity confirmation of medicines quality, including measures for the elimination of excessive administrative barriers for registration of domestic pharmaceuticals and ensuring proper control over their quality;
- improvement of the system of specialists training for the pharmaceutical industry, including the creation of new study programs in accordance with international standards.

The Strategy focuses on creating the necessary conditions for the development of pharmaceutical enterprises and scientific-research centers in the territory of Russia and their transition to the innovative model of development [9].

The increase of the share of products of domestic production in total consumption in the domestic market can be achieved with simultaneous application of two interconnected strategies:

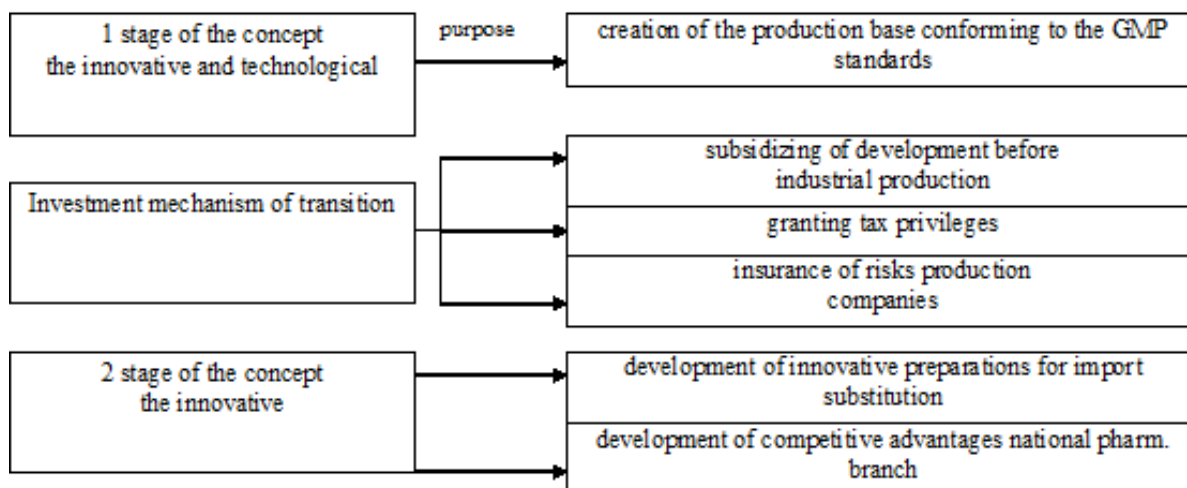
- import substitution through playing the best foreign samples of medicines with the help of mastering the technologies of their production;
- innovative development through the development of domestic original drugs and medical products on the basis of the technology, not inferior to the best foreign.

Innovative concept of development of pharmaceutical complex

For today within Strategy “Pharma 2020” it is offered to carry out introduction of new innovative and investment model of development to two stages: the first stage is investment, and the second stage is innovative.

However, it should be noted that it isn't absolutely correct to divide stages on innovative and investment as the investment component mediates all stages of innovative process. In this regard, we offer the new innovative and investment concept of development of the Russian pharmaceutical branch which is schematically submitted in Fig. 1.

Fig. 1 - Innovative and investment concept of development of pharmaceutical complex



The first stage of the innovative and investment concept is urged to increase competitiveness of the Russian generic preparations and to arrange production of innovative preparations according to the license for territories of the Russian Federation. At this stage it is necessary to carry out investment in development of the production base conforming to the GMP standards.

At the second stage development of the Russian innovative preparations, including for import substitution that assumes huge investments into creation and development of innovative molecules, medicinal substances and finished pharmaceutical products is supposed already. Development of the investment mechanism by means of which the company could interest in production of innovative medicines is necessary for transition to the second stage. Within the developed concept before domestic pharmaceutical industry there are three main objectives.

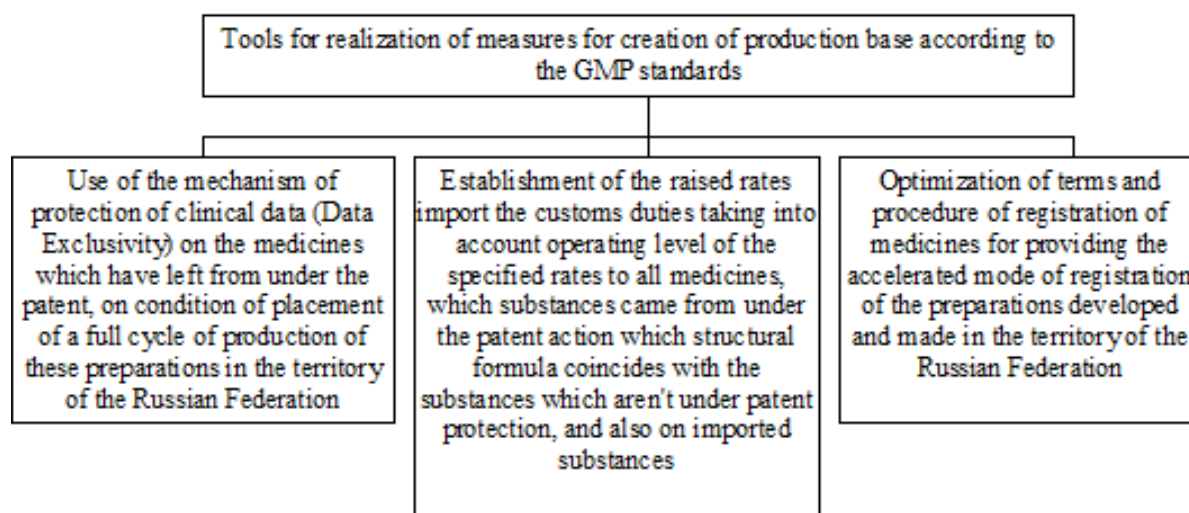
The first task in this branch is development of the modern production base conforming to the GMP standards, allowing with high efficiency to make medicinal substances and ready medicinal forms.

Measures for objective realization the following:

- to eliminate an existing competitive inequality between local and foreign pharmaceutical producers in the Russian Federation, including in a standard legal framework;
- to introduce obligatory requirements to rules of production of the medicines (GMP) identical to the international;
- to modernize and approve by the Pharmacopoeia of the Russian Federation the collection of the official documents providing appropriate quality of medicines, harmonized with the European Pharmacopoeia;
- to replace requirements of carrying out preregistration examination of quality of medicines with examination within procedure of preliminary state quality control;
- to enter requirements of providing the registration file of medicine in the CTD format (Common Technical Document);
- to modernize system of preparation of highly qualified specialists in the field of development and production of medicines;
- to accept the documents regulating development of medicines according to the international standards of appropriate laboratory and clinical practice (GLP and GCP);
- to organize functioning of federal laboratories for implementation of the state quality control and safety of medicines;
- to develop and accept necessary changes in the legislation of the Russian Federation and the relevant normative legal acts, to development of state programs of the Russian Federation in the field of provision of medicines.

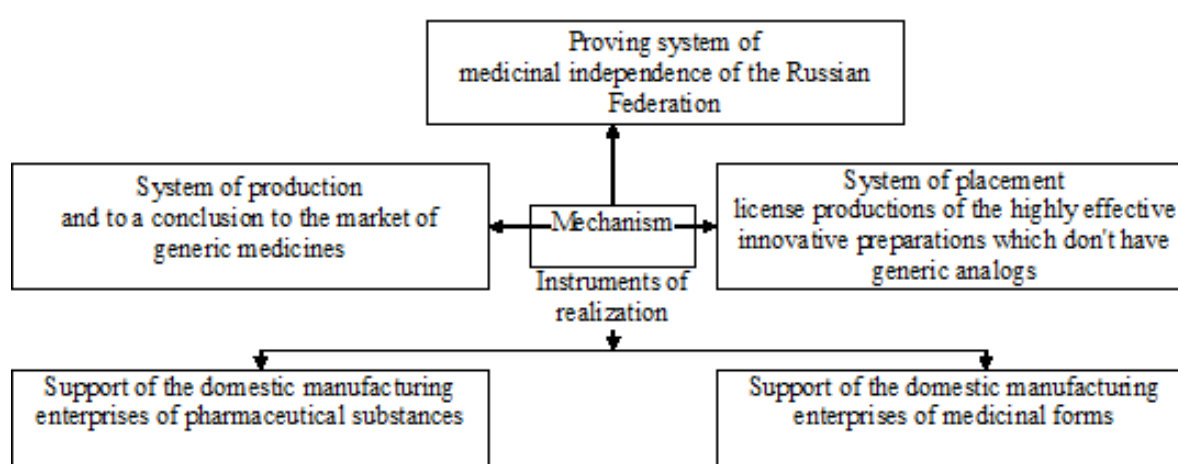
The main tools for realization of the above measures are presented in Fig. 2.

Fig. 2 - Tools for realization of measures for creation of the modern production base conforming to the GMP standards



The second task consists in formation of an effective market mechanism on hi-tech import substitution of medicines. Statement of the second task assumes creation of three systems (see Fig. 3).

Fig. 3 - The import substitution mechanism in the pharmaceutical market



The third task consists in realization of the measures aimed at the development of national pharmaceutical branch and implementation of its transition to innovative model of development.

The way of realization of an objective - infrastructure creation for development of innovative preparations, by means of tools is given below:

- large-scale state support of the research and development directed on creation of import-substituting medicines, including by regular carrying out competitions among small innovative firms on development of new medicines with the subsequent guaranteed purchase by the state of the created preparations;
- assignment for creation of specialized financial instruments for the research and development financing on development of innovative medicines and pharmaceutical substances, including grants for the small innovative enterprises;
- stimulation of introduction of modern research technologies, including on the basis of high-performance laboratory researches;
- stimulation of effective patent researches and monitoring of the international markets;
- improvement of the procedures regulating carrying out preclinical and clinical tests;
- preparation of research shots of new generation with use of training and the western experts.

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